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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,360	08/18/2006	Jim Jannes	0641-0278PUS1	8842
2292	7590	09/13/2007	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			KOSSON, ROSANNE	
		ART UNIT	PAPER NUMBER	
		1652		
		NOTIFICATION DATE	DELIVERY MODE	
		09/13/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/563,360	JANNES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 18 August 2006.  
2a)  This action is **FINAL**.                  2b)  This action is non-final.  
3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

- 4)  Claim(s) 1-4, 6, 7, 9-11, 13, 17, 35, 38, 40, 49, 50, 115 and 130-134 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) See *Continuation Sheet* are subject to restriction and/or election requirement.

## **Application Papers**

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_ .  
5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_\_

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-4,6,7,9-11,13,17,35,38,40,49,50,115 and 130-134.

**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 6, 7, 9, 130 and 131, drawn to a method of identifying a subject who is predisposed to ischemic stroke.

Group II, claim(s) 10, 11, 13, 17, 35, 38, 40, 132 and 133, drawn to a method of identifying a subject who is predisposed to small vessel occlusion.

Group III, claim(s) 49, 50 and 134, drawn to a method of treating a disease associated with small vessel occlusion.

Group IV, claim(s) 115, drawn to a polynucleotide comprising SEQ ID NO: 3.

Group V, claim(s) 115, drawn to a polynucleotide comprising SEQ ID NO: 4.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The requirement of unity of invention is not fulfilled because there is no technical relationship among these inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Therefore, a technical relationship is lacking among the claimed inventions involving one or more special technical features. The technical feature that links the five groups of inventions is t-PA.

The inventions of Groups I-V do not share the common special technical feature of t-PA, because Degen et al. ("The human tissue plasminogen activator gene," J Biol Chem 261(15):6972-6985, 1986) disclose t-PA (human t-PA, see Abstract and pp. 6981-6984).

Thus, the technical feature of t-PA does not define the invention over the prior art. Because the common technical feature is not novel (special) with respect to the cited reference, it is clear

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that the claims of Groups I-V lack a single common technical feature that defines them over the prior art.

Further, an international application containing claims to different categories of inventions will be considered to have unity of invention if the claims are drawn only to one of certain combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process (see 37 CFR 1.475(b)-(d)). In the instant case, the claims are drawn to multiple products and multiple processes, no combination of which including Group I may be considered for unity of invention, as Applicants have not claimed a product that is used in the method of Group I. Other groups are drawn to additional products and processes, and other combinations do not comply with the aforementioned Rules. Accordingly, a holding of lack of unity of invention is proper.

Regarding the different claimed sequences, Groups IV and V, Applicants must choose ONE polynucleotide from among those claimed as indicated in the different groups above.

Each sequence is a distinct invention requiring separate searches. THESE ARE NOT SPECIES. Each sequence is a chemically, structurally and functionally distinct molecule.

Therefore, the each of the polynucleotides is patentably distinct.

Moreover, each sequence requires a separate set of searches. Applicants should note that searching each sequence imposes a serious search burden. Currently, there are approximately eight different databases that accompany the results of a search for one discrete amino acid or nucleic acid sequence, and each result set from a particular database must be carefully considered. Each set of prior art has its own considerations with respect to anticipation and obviousness. Hence, the search for even two different polypeptides or polynucleotides in the databases, in addition to searching the organic molecule databases, would require extensive searching and review. Therefore, these inventions are patentably distinct.

Applicants are advised that a reply to this requirement must include an identification of the Group and sequence that are elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by a complete election.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows.

a) If Applicants elect Group II, in claim 11, Applicants must elect one of the diseases listed. This election will be applied to claim 40.

Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 10.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons. Claim 11 recites a large group of very different diseases, each of which has a different pathology, different symptoms, a different treatment and a different patient population, e.g., dementia vs. peripheral vascular disease vs. impotence. Because the claimed species are not art-recognized equivalents, a holding of lack of unity of invention is proper.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson  
Examiner, Art Unit 1652

rk/2007-04-04

*Rosanne Kosson*

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PRIMARY EXAMINER  
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1600